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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,086	07/15/2003	Yasuo Hirata	P/16-337	9265
2352	7590	02/17/2006	EXAMINER	
OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			FLANAGAN, BEVERLY MEINDL	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/621,086

Applicant(s)

HIRATA, YASUO

Examiner

Beverly M. Flanagan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10 and 12 is/are rejected.
- 7) ☒ Claim(s) 2-9, 11 and 13-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

BEVERLY M. FLANAGAN  
PRIMARY EXAMINER

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of the invention of Species I (claims 1-16) in the reply filed on June 23, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, Claims 17-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

### ***Previously Set Forth Rejections***

The 35 U.S.C. § 102(b) rejection of claims 1 and 10 as being anticipated by Snoke et al. (U.S. Patent No. 6,234,958) is hereby *maintained* and is reiterated below. The 35 U.S.C. § 103(a) rejection of claim 12 as being unpatentable over Snoke et al. (U.S. Patent No. 6,234,958) in view of Japanese Publication No. 2001-258819 is hereby *maintained* and is reiterated below.

**The following reiterated grounds of rejection are set forth:**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Snoke et al. (U.S. Patent No. 6,234,958).

**In regard to claim 1**, Snoke et al. teach a medical device introduction system 20 comprised of an introducer 30 that can be used to introduce an endoscope (see Figures 1-4). Introducer 30 includes a plurality of lumens 34-38 extending through the introducer body 31 for the passage of other tubular members (see Figures 1-4). As broadly as claimed, at least one of the lumens 34-38 has a predetermined degree of flexibility and length. Snoke et al. also teach a working channel device 80 that is preferably steerable (see col. 5, lines 60-65). **In regard to claim 10**, Snoke et al. teach an inflatable portion 43 located at the middle of introducer body 31 for the purpose of providing a lock for the introducer 30 to hold it in position (see Figures 2-4 and col. 7, lines 55-65).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snoke et al. (U.S. Patent No. 6,234,958) in view of Japanese Publication No. 2001-258819.

**In regard to claim 12**, Snoke et al. are silent as to the particulars of an endoscope passed through the insertion device 30. However, Japanese Publication No. 2001-258819 discloses an endoscope having a drum 12 upon which the insert part 8 of the endoscope is wound that is housed in a carrying case 7 (see Abstract, page 1). Japanese Publication No. 2001-258819 thus demonstrates that endoscopes would around drums and carrying cases for supporting the drums are well known in the art. Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide an endoscope used in the insertion device 30 of Snoke et al. with the drum and carrying case disclosed by Japanese Publication No. 2001-258819.

#### ***Allowable Subject Matter***

Claims 2-9, 11 and 13-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments filed December 1, 2005 have been fully considered but they are not persuasive. Applicant argues that the Snoke et al. reference fails to show or suggest an insertion unit guide member that is passed through or placed in a pipe as recited in claim 1. However, the recitation of "pipe" does not preclude the application of references used in medical setting, such as the device of Snoke et al., since use in a

medical setting can include (and when utilizing an endoscope inherently includes) use in a bodily lumen, which, as broadly as claimed, constitutes a pipe.

Applicant also argues that Snoke et al. do not disclose that the lumens provide a guide channel that has a diameter that permits other lumens to pass through the guide channel. However, the language of claim 1 does not preclude application of the Snoke et al. reference, where, as noted above, the reference meets all of the claimed limitations. In other words, as the claim is currently written, the device of Snoke et al. meets all of the claimed limitations since the claim does not require the structure as seen, for example, in Figure 3 of the instant invention (where the plurality of tubular members are connected end-to-end rather than side-by-side, as in Snoke et al.). Accordingly, given the broadest possible interpretation of the claims, Snoke et al. meets the claimed limitations set forth in claim 1 of the instant invention.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

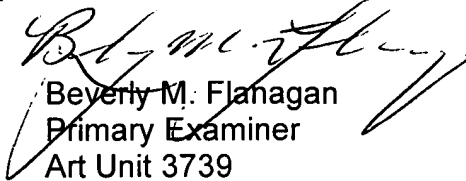
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Beverly M. Flanagan whose telephone number is (571) 272-4766. The examiner can normally be reached on Mondays, Tuesdays and Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Beverly M. Flanagan  
Primary Examiner  
Art Unit 3739

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